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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,033

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Ole Jacob Elle

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

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3766

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,033	<b>Applicant(s)</b> ELLE ET AL.	
	<b>Examiner</b> Frances P. Oropeza	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/13/2007 (Election).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2004 and 13 December 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/24/04, 11/22/06</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/ Restriction***

1. The election was made without traverse in the reply filed on 12/13/2007. The Applicant elected to prosecute Invention I. comprising claims 1-8 and newly added claims 23-25.

The claims not elected were cancelled.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 5, 7 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al. (U.S. Patent No. 6,115,630) (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al.).

Stadler et al. disclose a method and apparatus for properly orienting monitored cardiac information relating to ischemia (abstract; column1 @ 27-33). An accelerometer is implanted at the apex of the heart. The measured endocardial acceleration signal correlates well with periods of coronary occlusion, recognized to be periods of ischemia (column 28, line 62 - column 29, line 8).

As related to instant claim 7, data collected that relates to detection ischemia is stored in memory for later uplink telemetry transmission (Figure 2 – 120) and for analysis by the physician (column 12, lines 31-33; column 13, lines 8-36).

Stadler et al. incorporate by reference U.S. Patent No. 5,480,412 to Mouchawar et al. (column 28, line 63 – column 29, line 8).

Mouchawar et al. disclose a system and method for deriving hemodynamic signals from a cardiac wall motion sensor, and integrating the signals over time to derive velocity/ speed and acceleration (abstract). The motion sensor is mounted at the distal end of an implantable lead (column. 4, lines 15-26).

As related to instant claim 7, a telemetry system (Figure 3 – 314) enables communication between the implanted device and the external programmer (column 9, lines 16-21).

Mouchawar et al. incorporate by reference U.S. Patent No. 5,628,777 to Moberg et al. (column 2, lines 48-57; column 6, lines 4-6).

Moberg et al. disclose implantable leads that comprising accelerometer-based cardiac wall motion sensors (abstract). The electrode may be a patch electrode (Figures 3-6 - 60, 160, 260, 360) comprising a motion sensor (Figure 3-6 - 68, 168, 268, 368; column 7, line 30 – column 9, line 48). The patch electrode is sutured in the cardiac wall of the right and/ or left ventricular in the region selected to be monitored, or at the selected position corresponding to the area that is supplied by the selected vessel (column 8, lines 65-67; column 21, lines 18-22).

As related to instant claims 4 and 24, the lead may also be an endocardial lead comprising a piezoelectric wall motion sensor (Figure 8 – 568; Figures 13-15 - 214; column 14, lines 10-16) and a helically-shaped tip electrode (Figure 8 - 118), the helical shape of the

electrode making the electrode removable from its position without requiring surgical intervention.

As related to instant claim 5, the accelerometer-based cardiac wall motion sensors are sensitive along three perpendicular axis (column 3, lines 33-43).

As related to instant claim 7, a telemetry network (256, 258) enables communication between the implanted device and the external device (Figure 18; column 19, lines 3-10).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. (U.S. Patent No. 6,115,630) in view of Matsumoto (U.S. Patent No. 6,328,698).

As discussed in paragraph 3 of this action, Stadler et al. disclose the claimed invention except for the method being performed post operatively in connection with a bypass operation where the area of the heart monitored by the motion sensor is associated with a “revascularised” coronary artery.

Matsumoto teaches a diagnostic system for diagnosing cardiac disease using a three axial accelerometer for the purpose of detecting displacement of the chest wall and teaches monitoring the patient after a bypass procedure where cardiac coronary vascular flow is improved. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the three axial accelerometer for the purpose of monitoring a patient after a bypass procedure where cardiac coronary vascular flow is improved in the Stadler et al. system in order to provide a proven means to evaluate the effectiveness of a procedure involving a bypass, and in order to follow the patient's cardiac performance closely during the post-operative period ( abstract; column 2, lines 45-50; column 3, lines 45-48, 63-64; column 9, lines 52-64).

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. (U.S. Patent No. 6,115,630) in view of Dickinson et al. (U.S. Patent No. 6,275,724).

As discussed in paragraph 3 of this action, Stadler et al. disclose the claimed invention except for the motion sensor comprising a gyroscope.

Dickinson et al. teach cardiac monitoring using a three-axis solid state gyroscope or a three-axis accelerometer for the purpose of monitoring the position and location of the catheter.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a three-axis solid state gyroscope in the Stadler et al. system in order to provide a known alternative sensor to the accelerometer presently used in the system so the system user has the option to choose the most appropriate motion sensor for the application, and in order that the invention disclosed by Stadler et al. identify additional applications in cardiac medicine (column 1, lines 4-14; column 5, lines 51-54; column 6, lines 2-4; column 9, lines 52-61).

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. (U.S. Patent No. 6,115,630) in view of Hess (U.S. Patent No. 6,328,698).

Stadler et al. teach an accelerometer implanted at the apex of the heart. The measured endocardial acceleration signal correlate well with periods of coronary occlusion recognized to be period of ischemia (column 28, line 62 - column 29, line 8).

As discussed in the preceding paragraph and in paragraph 3 of this action, Stadler et al. disclose the claimed invention except for the motion sensor being incorporated in a temporary pacemaker electrode.

Hess teaches interim pacing using a temporary pacemaker electrode for the purpose of providing stimulus to the heart during medical procedure such as replacement of a cardiac pacemaker. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a temporary lead including a motion sensor in the Stadler et al. system in order to effectively monitor the patient after a procedure in order to be able to rapidly respond to any cardiac pacing or cardiac ischemia issues that might arises (column 1, lines 37-44).

***Claims Objections***

8. Claims 1 and 25 are objected to because of the following informalities:

In claim 1, line 4, the period after "position",

In claim 3, line 3, it appears the spelling of "vascularised" should be corrected, and

In claim 25, line 5, it appears "reflect" should be plural.

Appropriate correction is required.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Carl H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST.

The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/  
Patent Examiner, Art Unit 3766

**/Carl H. Layno/**

**Supervisory Patent Examiner, Art Unit 3766**